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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,378

07/14/2003

Steven Walkley

2543-1-022PCT/CIP

5426

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10/30/2006

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/619,378	<b>Applicant(s)</b> WALKLEY, STEVEN	
	<b>Examiner</b> Daniel M. Sullivan	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21,22,25,26,28,29,32,33,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,22,25,26,28,29,32,33,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>20060801</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 18 August 2006 in response to the Final Office Action mailed 15 May 2006. Claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 were considered in the 15 May Office Action. Claims 21, 28, 36 and 37 were amended in the 18 August Paper. Claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 are pending and under consideration.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2006 has been entered.

#### ***Response to Amendment and Arguments***

##### **Claim Rejections - 35 USC § 112**

Rejection of claims 21, 22, 28, 29, 36 and 37 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is **withdrawn** in view of the amendment of the claims such that they are now limited to administering an imino sugar inhibitor of glucosylceramide synthase.

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Rejection of claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is **withdrawn** in view of the amendment of the claims such that they are now limited to administering an imino sugar inhibitor of glucosylceramide synthase in an amount sufficient to provide the symptomatic relief recited in the claims.

### *New Grounds*

#### Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The claims are directed to methods of altering disease processes in “mucopolysaccharide disease”. The specification does not contain a literal antecedent basis for “mucopolysaccharide disease”. Instead, the specification describes “mucopolysaccharidosis disease”. (See, e.g., ¶11.) Applicant is required to either amend the specification to provide antecedent basis for the claim limitation, while being careful to avoid introducing new matter, or amend the claim to use the limitation “mucopolysaccharidosis disease”, which is the term used in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 21, 25, 26, 28, 32, 33, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of “mucopolysaccharide disease”. The disclosure provides no definition of what constitutes a mucopolysaccharide disease but instead provides detailed description of mucopolysaccharidosis disease. It is unclear from the disclosure whether the terms mucopolysaccharide disease and mucopolysaccharidosis disease are being used interchangeably or whether mucopolysaccharide disease embraces subject matter other than what is described for mucopolysaccharidosis disease. As it is unclear from the disclosure what is encompassed by the “mucopolysaccharide disease” of the claims, the metes and bounds of the claims are unclear.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 22, 25, 28, 29, 32, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Fan et al. U.S. Pub. No. 2002/0035072 A1 or Meeker et al. U.S. Pub. No. 2002/0095135.

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The instant claims are directed to a method of slowing mucopolysaccharide disease progression, reducing neuronal glycolipid storage in mucopolysaccharide disease, reducing pathological features resulting from glycolipid accumulation in a patient with a mucopolysaccharide disease and a method of improving survival of a patient with a mucopolysaccharide disease.

Fan et al. contemplates treating patients having various mucopolysaccharidosis diseases, including Hurler-Scheie disease, Hunter disease, and Sanfilippo disease by administering imino sugar inhibitors of glucosylceramide synthase such as N-butyl-1-deoxygalactonojirimycin. (See especially, Table 1, ¶0015, ¶0031, ¶0032, ¶0073 and Table 2.) Absent evidence to the contrary, the method of treating mucopolysaccharidosis diseases through the administration of inhibitors of glucosylceramide synthase would result in the outcomes recited in the instant claims. Thus, the teachings of Fan et al. anticipate the invention of independent claims 21, 28, 36 and 37. Furthermore, the various mucopolysaccharidosis diseases contemplated by fan et al. anticipate the diseases recited in claims 22 and 29. (See Table 1 of the instant specification.) Finally, the embodiment of the invention contemplated by Fan et al. wherein the inhibitor is N-butyl-1-deoxygalactonojirimycin anticipates the method of claims 25 and 32.

Thus, the teachings of Fan et al. anticipate each of the elements of the instant claims. Therefore, the claims are properly rejected under 35 USC §102(e) as anticipated by Fan et al.

Claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Meeker et al. U.S. Pub. No. 2002/0095135.

The claim limitations are described herein above.

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Meeker et al. contemplates treating patients having various mucopolysaccharidosis diseases, including MPS I-III by administering imino sugar inhibitors of glucosylceramide synthase such as N-butyldeoxynojirimycin and N-butyldeoxygalactonojirimycin. (See especially, ¶0041-0045, ¶0065, ¶0068, ¶0076, Table 1 and ¶0077.) Absent evidence to the contrary, the method of treating mucopolysaccharidosis diseases through the administration of inhibitors of glucosylceramide synthase would result in the outcomes recited in the instant claims. Thus, the teachings of Meeker et al. anticipate the invention of independent claims 21, 28, 36 and 37. Furthermore, the various mucopolysaccharidosis diseases contemplated by Meeker et al. anticipate the diseases recited in claims 22 and 29 and the embodiment of the invention contemplated by Meeker et al. wherein the inhibitor is N-butyldeoxynojirimycin or N-butyldeoxygalactonojirimycin anticipate the method of claims 25, 26, 32 and 33.

Thus, the teachings of Meeker et al. anticipate each of the elements of the instant claims. Therefore, the claims are properly rejected under 35 USC §102(e) as anticipated by Meeker et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.

Primary Examiner

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